

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

CHRISTINE HESS, on behalf of her minor child KADEN COTES,	:	
	:	
Plaintiff,	:	
	:	Civil Action No.: 2:10-CV-005199-CDJ
vs.	:	
	:	
GLAXOSMITHKLINE et al.	:	
	:	
Defendants.	:	
	:	

DEFENDANT GLAXOSMITHKLINE LLC, FORMERLY SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFFS' COMPLAINT

COMES NOW Defendant GlaxoSmithKline LLC, formerly SmithKline Beecham Corporation, d/b/a GlaxoSmithKline (“GSK”)¹ and hereby files this Answer and Affirmative Defenses to Plaintiffs’ Short-Form Complaint and to Plaintiffs’ Master Long-Form Complaint (collectively, “Plaintiffs’ Complaint”), respectfully showing the Court as follows:

ANSWERING PLAINTIFFS' SHORT-FORM COMPLAINT

1. Answering Paragraph 1 of Plaintiffs’ Short-Form Complaint, GSK admits that a lawsuit has been filed against it and other defendants by Plaintiff Christine Hess on behalf of Kaden Cotes. GSK denies any remaining allegations contained in Paragraph 1 of Plaintiffs’ Short-Form Complaint.

¹ Subsequent to the combination of Glaxo Wellcome plc and SmithKline Beecham p.l.c. (now known as SmithKline Beecham Limited) on December 27, 2000, SmithKline Beecham Corporation, a Pennsylvania corporation incorporated on June 29, 1929, made a fictitious name filing in the Commonwealth of Pennsylvania on January 16, 2001 to be known as GlaxoSmithKline.

SmithKline Beecham Corporation converted from a Pennsylvania corporation to a Delaware corporation and then subsequently converted to a limited liability company in Delaware changing its name to GlaxoSmithKline LLC with effect from October 27, 2009.

2. Answering Paragraph 2 of Plaintiffs' Short-Form Complaint, GSK admits that a lawsuit has been filed against it and other defendants by Plaintiff Christine Hess on behalf of Kaden Cotes. GSK is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 2, including subparagraphs (A), (B), (C), (D), or (E) of Plaintiffs' Short-Form Complaint and therefore denies the same.

3. GSK is without knowledge and information sufficient to form a belief as to the truth of the allegations contained in Paragraph 3 of Plaintiffs' Short-Form Complaint and therefore denies the same.

4. GSK is without knowledge and information sufficient to form a belief as to the truth of the allegations contained in Paragraph 4 of Plaintiffs' Short-Form Complaint and therefore denies the same.

5. GSK is without knowledge and information sufficient to form a belief as to the truth of the allegations contained in Paragraph 5 of Plaintiffs' Short-Form Complaint and therefore denies the same.

6. Answering Paragraph 6 of Plaintiffs' Short-Form Complaint, GSK denies that it is responsible in any way for causing or contributing to the injuries or damages alleged in Plaintiffs' Short-Form Complaint. GSK is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 6 of Plaintiffs' Short-Form Complaint and therefore denies the same.

7. Answering Paragraph 7 of Plaintiffs' Short-Form Complaint, GSK admits that Plaintiffs have asserted the claims set forth in Paragraph 7 of Plaintiffs' Short Form Complaint. GSK denies that it is responsible in any way for causing or contributing to the injuries or

damages alleged in Plaintiffs' Short-Form Complaint. GSK denies any remaining allegations contained in Paragraph 7 of Plaintiffs' Short-Form Complaint.

8. Answering Paragraph 8 of Plaintiffs' Short-Form Complaint, GSK admits that Plaintiffs claim to have asserted all of the counts referenced in Paragraph 7 of Plaintiffs' Short-Form Complaint, as set forth in the Master Long-Form Complaint, against the additional named defendants. However, GSK denies that Plaintiffs have pled any specific facts or allegations directed at any defendant, other than GSK, as is required by Paragraph 2.C.3 of Case Management Order No. 1 of In re Paxil Pregnancy Cases, February Term 2007, No. 3220, Philadelphia Court of Common Pleas. GSK denies any remaining allegations contained in Paragraph 8 of Plaintiffs' Short-Form Complaint.

ANSWERING THE SECTION OF PLAINTIFFS'
MASTER LONG-FORM COMPLAINT TITLED "PLAINTIFFS"

1. Answering Paragraph 1 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs' Long-Form Complaint was filed for plaintiffs in the "Paxil Pregnancy Cases" pending in the Philadelphia Court of Common Pleas Mass Tort Program ("MTP") under the caption In re: Paxil Pregnancy Cases, and that Plaintiffs Christine Hess and Kaden Cotes adopted certain causes of action in their Short-Form Complaint. GSK is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 1 of Plaintiffs' Long-Form Complaint and therefore denies the same.

2. Answering Paragraph 2 of Plaintiffs' Long-Form Complaint, GSK admits that Christine Hess has filed this lawsuit on behalf of Kaden Cotes. GSK denies that it is responsible in any way for causing or contributing to any alleged injuries or damages to Kaden Cotes. GSK denies any remaining allegations contained in Paragraph 2 of Plaintiffs' Long-Form Complaint and therefore denies the same.

3. Answering Paragraph 3 of Plaintiffs' Long-Form Complaint, GSK admits that Christine Hess has filed this lawsuit on behalf of Kaden Cotes. GSK denies that it is responsible in any way for causing or contributing to any alleged injuries or damages to Kaden Cotes. GSK denies any remaining allegations contained in Paragraph 3 of Plaintiffs' Long-Form Complaint.

4. GSK denies the allegations contained in Paragraph 4 of Plaintiffs' Long-Form Complaint.

5. Answering Paragraph 5 of Plaintiffs' Long-Form Complaint, GSK admits that "Plaintiffs" as used in Plaintiffs' Long-Form Complaint refers collectively to the "Infant Plaintiffs," "Mother Plaintiffs," and "Father Plaintiffs," as defined in Paragraphs 2 through 4 of Plaintiffs' Long-Form Complaint. GSK denies any remaining allegations contained in Paragraph 5 of Plaintiffs' Long-Form Complaint.

ANSWERING THE SECTION OF PLAINTIFFS'
MASTER LONG-FORM COMPLAINT TITLED "DEFENDANT"

6. Answering Paragraph 6 of Plaintiffs' Long-Form Complaint, GSK denies that it is a Pennsylvania corporation with its principal place of business in Philadelphia, Pennsylvania. GSK admits that it has marketed, promoted, conducted clinical trials involving, and, for the purposes of this litigation, manufactured certain over-the-counter and prescription pharmaceuticals. GSK also admits that it has marketed, promoted, conducted clinical trial involving, and, for the purposes of this litigation, manufactured the prescription pharmaceutical paroxetine hydrochloride, which is marketed and sold in the United States under the trade name Paxil® ("Paxil"), and that Paxil is an antidepressant. GSK denies any remaining allegations contained in Paragraph 6 of Plaintiffs' Long-Form Complaint.

**ANSWERING THE SECTION OF PLAINTIFFS' MASTER
LONG-FORM COMPLAINT TITLED "JURISDICTIONAL ALLEGATIONS"**

7. Answering Paragraph 7 of Plaintiffs' Long-Form Complaint, GSK denies that it is a Pennsylvania corporation. GSK states that the remaining allegations contained in Paragraph 7 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law.

**ANSWERING THE SECTION OF PLAINTIFFS' MASTER
LONG-FORM COMPLAINT TITLED "GENERAL ALLEGATIONS"**

8. Answering Paragraph 8 of Plaintiffs' Long-Form Complaint, GSK admits that it marketed, promoted, and for purposes of this litigation, manufactured the prescription pharmaceutical paroxetine hydrochloride, which is marketed and sold in the United States under the trade names Paxil, Paxil Oral Suspension Formula, and Paxil CR™ ("Paxil CR"). GSK admits that Paxil, Paxil Oral Suspension Formula, and Paxil CR are generally classified as selective serotonin reuptake inhibitors ("SSRIs"). GSK admits that on December 29, 1992, the United States Food and Drug Administration ("FDA") approved Paxil as a safe and effective prescription medication for the treatment of depression in adult patients. GSK denies any remaining allegations in Paragraph 8 of Plaintiffs' Long-Form Complaint.

9. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 9 of Plaintiffs' Long-Form Complaint and therefore denies the same.

10. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 10 of Plaintiffs' Long-Form Complaint and in particular any allegations regarding Kaden Cotes' alleged congenital defects and therefore denies the same. GSK denies any remaining allegations contained in Paragraph 10 of Plaintiffs' Long-Form Complaint.

11. GSK denies the allegations contained in Paragraph 11 of Plaintiffs' Long-Form Complaint.

12. GSK denies the allegations contained in Paragraph 12 of Plaintiffs' Long-Form Complaint.

13. GSK denies the allegations contained in Paragraph 13 of Plaintiffs' Long-Form Complaint.

14. GSK denies the allegations contained in Paragraph 14 of Plaintiffs' Long-Form Complaint.

15. Answering Paragraph 15 of Plaintiffs' Long-Form Complaint, GSK admits that the federal laws and regulations governing pharmaceutical products and GSK's obligations with respect to such products speak for themselves. GSK denies any remaining allegations contained in Paragraph 15 of Plaintiffs' Long-Form Complaint.

16. GSK denies the allegations contained in Paragraph 16 of Plaintiffs' Long-Form Complaint.

17. GSK states that the allegations contained in Paragraph 17 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies the allegations contained in Paragraph 17 of Plaintiffs' Long-Form Complaint.

**ANSWERING THE SECTION OF PLAINTIFFS' MASTER LONG-FORM
COMPLAINT TITLED "COUNT I: NEGLIGENCE & NEGLIGENCE PER SE"**

18. GSK incorporates by reference, as if set forth fully herein, its responses to all preceding Paragraphs in this Answer and each and every one of its defenses.

19. GSK states that the allegations contained in Paragraph 19 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as

a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies the allegations contained in Paragraph 19 of Plaintiffs' Long-Form Complaint.

20. Answering Paragraph 20 of Plaintiffs' Long-Form Complaint, GSK denies that it is responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Complaint. GSK further states that the allegations contained in Paragraph 20 of Plaintiffs' Long-Form Complaint, including subparagraphs (a) through (j), are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies the allegations contained in Paragraph 20 of Plaintiffs' Long-Form Complaint, including subparagraphs (a) through (j).

21. GSK states that the allegations contained in Paragraph 21 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies the allegations contained in Paragraph 21 of Plaintiffs' Long-Form Complaint.

22. GSK denies the allegations contained in Paragraph 22 of Plaintiffs' Long-Form Complaint.

23. Answering Paragraph 23 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 23 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies it is responsible in any way for causing or contributing to any alleged injuries or damages to Plaintiffs. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 23

of Plaintiffs' Long-Form Complaint, particularly as they relate to Kaden Cotes' injuries, and therefore denies the same.

24. Answering Paragraph 24 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 24 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies that it responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 24 of Plaintiffs' Long-Form Complaint and therefore denies the same.

25. Answering Paragraph 25 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 25 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies that it responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 25 of Plaintiffs' Long-Form Complaint and therefore denies the same.

26. Answering Paragraph 26 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 26 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is

required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies that it responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 26 of Plaintiffs' Long-Form Complaint and therefore denies the same.

27. GSK denies the allegations contained in Paragraph 27 of Plaintiffs' Long-Form Complaint.

The unnumbered WHEREFORE paragraph following Paragraph 27 is a prayer for relief to which GSK responds that Plaintiffs are not entitled to any relief from GSK, including all relief in this prayer for relief.

ANSWERING THE SECTION OF PLAINTIFFS' MASTER LONG-FORM COMPLAINT TITLED "COUNT II: NEGLIGENT PHARMACO-VIGILANCE"

28. GSK incorporates by reference, as if set forth fully herein, its responses to all preceding Paragraphs in this Answer and each and every one of its defenses.

29. GSK states that the allegations contained in Paragraph 29 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK admits that GSK's duties and obligations, if any, under applicable law and/or federal law and regulations governing pharmaceutical products speak for themselves. GSK denies any remaining allegations contained in Paragraph 29 of Plaintiffs' Long-Form Complaint.

30. GSK denies the allegations contained in Paragraph 30 of Plaintiffs' Long-Form Complaint.

31. Answering Paragraph 31 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 31 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies it is responsible in any way for causing or contributing to any alleged injuries or damages to Plaintiffs. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 31 of Plaintiffs' Long-Form Complaint, particularly as they relate to Kaden Cotes' injuries, and therefore denies the same.

32. Answering Paragraph 32 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 32 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies that it responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 32 of Plaintiffs' Long-Form Complaint and therefore denies the same.

33. Answering Paragraph 33 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 33 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies that it responsible in any way for causing or

contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 33 of Plaintiffs' Long-Form Complaint and therefore denies the same.

34. Answering Paragraph 34 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 34 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegation directed to GSK, GSK denies that it responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 34 of Plaintiffs' Long-Form Complaint and therefore denies the same.

35. GSK denies the allegations contained in Paragraph 35 of Plaintiffs' Long-Form Complaint.

The unnumbered WHEREFORE paragraph following Paragraph 35 is a prayer for relief to which GSK responds that Plaintiffs are not entitled to any relief from GSK, including all relief in this prayer for relief.

**ANSWERING THE SECTION OF PLAINTIFFS' MASTER
LONG-FORM COMPLAINT TITLED "COUNT III: STRICT LIABILITY"**

36. GSK incorporates by reference, as if set forth fully herein, its responses to all preceding Paragraphs in this Answer and each and every one of its defenses.

37. Answering Paragraph 37 of Plaintiffs' Long-Form Complaint, GSK admits that it marketed, promoted, and for purposes of this litigation, manufactured the prescription

pharmaceutical paroxetine hydrochloride, which is marketed and sold in the United States under the trade name Paxil. GSK states that the remaining allegations contained in Paragraph 37 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. GSK denies any remaining allegations contained in Paragraph 37 of Plaintiffs' Long-Form Complaint.

38. Answering Paragraph 38 of Plaintiffs' Long-Form Complaint, GSK admits that, for purposes of this litigation, it manufactures the prescription pharmaceutical paroxetine hydrochloride, which is marketed and sold in the United States under the trade name Paxil. GSK denies the remaining allegations contained in Paragraph 38 of Plaintiffs' Long-Form Complaint.

39. Answering Paragraph 39 of Plaintiffs' Long-Form Complaint, GSK admits that, for purposes of this litigation, it manufactured the prescription pharmaceutical paroxetine hydrochloride, which is marketed and sold in the United States under the trade name Paxil. GSK denies the remaining allegations contained in Paragraph 39 of Plaintiffs' Long-Form Complaint.

40. Answering Paragraph 40 of Plaintiffs' Long-Form Complaint, GSK admits that, for purposes of this litigation, it manufactured the prescription pharmaceutical paroxetine hydrochloride, which is marketed and sold in the United States under the trade name Paxil. GSK denies the remaining allegations contained in Paragraph 40 of Plaintiffs' Long-Form Complaint.

41. Answering Paragraph 41 of Plaintiffs' Long-Form Complaint, GSK admits that, for purposes of this litigation, it manufactured the prescription pharmaceutical paroxetine hydrochloride, which is marketed and sold in the United States under the trade name Paxil. GSK denies the remaining allegations contained in Paragraph 41 of Plaintiffs' Long-Form Complaint.

42. Answering Paragraph 42 of Plaintiffs' Long-Form Complaint, GSK admits that, for purposes of this litigation, it manufactured the prescription pharmaceutical paroxetine

hydrochloride, which is marketed and sold in the United States under the trade name Paxil. GSK denies the remaining allegations contained in Paragraph 42 of Plaintiffs' Long-Form Complaint.

43. Answering Paragraph 43 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 43 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies it is responsible in any way for causing or contributing to any alleged injuries or damages to Plaintiffs. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 43 of Plaintiffs' Long-Form Complaint, particularly as they relate to Kaden Cotes' injuries, and therefore denies the same.

44. Answering Paragraph 44 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 44 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies that it responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 44 of Plaintiffs' Long-Form Complaint and therefore denies the same.

45. Answering Paragraph 45 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 45 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is

required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies that it responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 45 of Plaintiffs' Long-Form Complaint and therefore denies the same.

46. Answering Paragraph 46 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 46 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies that it responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 46 of Plaintiffs' Long-Form Complaint and therefore denies the same.

47. GSK denies the allegations contained in Paragraph 47 of Plaintiffs' Long-Form Complaint.

The unnumbered WHEREFORE paragraph following Paragraph 47 is a prayer for relief to which GSK responds that Plaintiffs are not entitled to any relief from GSK, including all relief in this prayer for relief.

**ANSWERING THE SECTION OF PLAINTIFFS' MASTER
LONG-FORM COMPLAINT TITLED "COUNT IV: FAILURE TO WARN"**

48. GSK incorporates by reference, as if set forth fully herein, its responses to all preceding Paragraphs in this Answer and each and every one of its defenses.

49. GSK denies the allegations contained in Paragraph 49 of Plaintiffs' Long-Form Complaint.

50. GSK denies the allegations contained in Paragraph 50 of Plaintiffs' Long-Form Complaint.

51. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 51 of Plaintiffs' Long-Form Complaint regarding knowledge of the public and medical community and therefore denies the same. GSK denies the remaining allegations contained in Paragraph 51 of Plaintiffs' Long-Form Complaint.

52. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 52 of Plaintiffs' Long-Form Complaint and therefore denies the same.

53. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 53 of Plaintiffs' Long-Form Complaint and therefore denies the same.

54. Answering Paragraph 54 of Plaintiffs' Long-Form Complaint, GSK admits that the FDA-approved labeling for Paxil, which has changed over time, is in writing and speaks for itself. GSK also admits that the federal laws and regulations governing pharmaceutical products and GSK's obligations with respect to such products speak for themselves. GSK denies any remaining allegations contained in Paragraph 54 of Plaintiffs' Long-Form Complaint.

55. GSK denies the allegations contained in Paragraph 55 of Plaintiffs' Long-Form Complaint.

56. GSK denies the allegations contained in Paragraph 56 of Plaintiffs' Long-Form Complaint.

57. Answering Paragraph 57 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 57 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies it is responsible in any way for causing or contributing to any alleged injuries or damages to Plaintiffs. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 57 of Plaintiffs' Long-Form Complaint, particularly as they relate to Kaden Cotes' injuries, and therefore denies the same.

58. Answering Paragraph 58 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 58 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies that it responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 58 of Plaintiffs' Long-Form Complaint and therefore denies the same.

59. Answering Paragraph 59 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 59 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies that it responsible in any way for causing or

contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 59 of Plaintiffs' Long-Form Complaint and therefore denies the same.

60. Answering Paragraph 60 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 60 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies that it responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 60 of Plaintiffs' Long-Form Complaint and therefore denies the same.

61. GSK denies the allegations contained in Paragraph 61 of Plaintiffs' Long-Form Complaint.

The unnumbered WHEREFORE paragraph following Paragraph 61 is a prayer for relief to which GSK responds that Plaintiffs are not entitled to any relief from GSK, including all relief in this prayer for relief.

**ANSWERING THE SECTION OF PLAINTIFFS'
MASTER LONG-FORM COMPLAINT TITLED "COUNTS V & VI:
BREACH OF EXPRESS AND IMPLIED WARRANTY"**

62. GSK incorporates by reference, as if set forth fully herein, its responses to all preceding Paragraphs in this Answer and each and every one of its defenses.

63. Answering Paragraph 63 of Plaintiffs' Long-Form Complaint, GSK admits that GSK's promotional materials for Paxil speak for themselves. GSK denies any remaining allegations contained in Paragraph 63 of Plaintiffs' Long-Form Complaint.

64. Answering Paragraph 64 of Plaintiffs' Long-Form Complaint, GSK admits that GSK's promotional materials for Paxil speak for themselves. GSK denies any remaining allegations contained in Paragraph 64 of Plaintiffs' Long-Form Complaint.

65. GSK denies the allegations contained in Paragraph 65 of Plaintiffs' Long-Form Complaint.

66. Answering Paragraph 66 of Plaintiffs' Long-Form Complaint, GSK admits that GSK's promotional materials for Paxil speak for themselves. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Christine Hess' alleged use of Paxil and therefore denies the same. GSK denies any remaining allegations contained in Paragraph 66 of Plaintiffs' Long-Form Complaint.

67. GSK denies the allegations contained in Paragraph 67 of Plaintiffs' Long-Form Complaint.

68. Answering Paragraph 68 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 68 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies it is responsible in any way for causing or contributing to any alleged injuries or damages to Plaintiffs. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 68

of Plaintiffs' Long-Form Complaint, particularly as they relate to Kaden Cotes' injuries, and therefore denies the same.

69. Answering Paragraph 69 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 69 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies that it responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 69 of Plaintiffs' Long-Form Complaint and therefore denies the same.

70. Answering Paragraph 70 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 70 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies that it responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 70 of Plaintiffs' Long-Form Complaint and therefore denies the same.

71. Answering Paragraph 71 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 71 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is

required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies that it responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 71 of Plaintiffs' Long-Form Complaint and therefore denies the same.

72. GSK denies the allegations contained in Paragraph 72 of Plaintiffs' Long-Form Complaint.

The unnumbered WHEREFORE paragraph following Paragraph 72 is a prayer for relief to which GSK responds that Plaintiffs are not entitled to any relief from GSK, including all relief in this prayer for relief.

**ANSWERING THE SECTION OF PLAINTIFFS' MASTER
LONG-FORM COMPLAINT TITLED "COUNT VII: FRAUD"**

73. GSK incorporates by reference, as if set forth fully herein, its responses to all preceding Paragraphs in this Answer and each and every one of its defenses.

74. Answering Paragraph 74 of Plaintiffs' Long-Form Complaint, GSK admits that it marketed, promoted, and for purposes of this litigation, manufactured the prescription pharmaceutical paroxetine hydrochloride, which is marketed and sold in the United States under the trade name Paxil. GSK states that the remaining allegations contained in Paragraph 74 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. GSK denies any remaining allegations contained in Paragraph 74 of Plaintiffs' Long-Form Complaint.

75. Answering Paragraph 75 of Plaintiffs' Long-Form Complaint, GSK admits that GSK's promotional materials for Paxil speak for themselves. GSK denies the remaining allegations contained in Paragraph 75 of Plaintiffs' Long-Form Complaint.

76. Answering Paragraph 76 of Plaintiffs' Long-Form Complaint, GSK admits that GSK's promotional materials for Paxil speak for themselves. GSK denies the remaining allegations contained in Paragraph 76 of Plaintiffs' Long-Form Complaint.

77. Answering Paragraph 77 of Plaintiffs' Long-Form Complaint, GSK admits that GSK's promotional materials for Paxil speak for themselves. GSK denies the remaining allegations contained in Paragraph 77 of Plaintiffs' Long-Form Complaint, including subparagraphs (a) through (b).

78. GSK denies the allegations contained in Paragraph 78 of Plaintiffs' Long-Form Complaint.

79. Answering Paragraph 79 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 79 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies it is responsible in any way for causing or contributing to any alleged injuries or damages to Plaintiffs. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 79 of Plaintiffs' Long-Form Complaint, particularly as they relate to Kaden Cotes' injuries, and therefore denies the same.

80. Answering Paragraph 80 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in

Paragraph 80 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies that it responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 80 of Plaintiffs' Long-Form Complaint and therefore denies the same.

81. Answering Paragraph 81 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 81 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies that it responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 81 of Plaintiffs' Long-Form Complaint and therefore denies the same.

82. Answering Paragraph 82 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 82 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies that it responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining

allegations contained in Paragraph 82 of Plaintiffs' Long-Form Complaint and therefore denies the same.

83. GSK denies the allegations contained in Paragraph 83 of Plaintiffs' Long-Form Complaint.

The unnumbered WHEREFORE paragraph following Paragraph 83 is a prayer for relief to which GSK responds that Plaintiffs are not entitled to any relief from GSK, including all relief in this prayer for relief.

ANSWERING THE SECTION OF PLAINTIFFS'
MASTER LONG-FORM COMPLAINT TITLED "COUNT VIII:
LOSS OF CONSORTIUM AND LOSS OF INCOME"

84. GSK incorporates by reference, as if set forth fully herein, its responses to all preceding Paragraphs in this Answer and each and every one of its defenses.

85. Answering Paragraph 85 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 85 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies that it responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 85 of Plaintiffs' Long-Form Complaint and therefore denies the same.

86. Answering Paragraph 86 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 86 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual

allegations directed to GSK, GSK denies that it responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 86 of Plaintiffs' Long-Form Complaint and therefore denies the same.

ANSWERING THE SECTION OF PLAINTIFFS' MASTER LONG-FORM COMPLAINT TITLED "COUNT IX: CAUSE OF ACTION FOR SURVIVAL"

87. GSK incorporates by reference, as if set forth fully herein, its responses to all preceding Paragraphs in this Answer and each and every one of its defenses.

88. Answering Paragraph 88 of Plaintiffs' Long-Form Complaint, GSK denies that it is responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK denies any remaining allegations contained in Paragraph 88 of Plaintiffs' Long-Form Complaint.

89. Answering Paragraph 89 of Plaintiffs' Long-Form Complaint, GSK denies that it is responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK denies any remaining allegations contained in Paragraph 89 of Plaintiffs' Long-Form Complaint.

ANSWERING THE SECTION OF PLAINTIFFS' MASTER LONG-FORM COMPLAINT TITLED "COUNT X: NEGLIGENCE DESIGN"

90. GSK incorporates by reference, as if set forth fully herein, its responses to all preceding Paragraphs in this Answer and each and every one of its defenses.

91. Answering Paragraph 91 of Plaintiffs' Long-Form Complaint, GSK admits that it marketed, promoted, and for purposes of this litigation, manufactured the prescription pharmaceutical paroxetine hydrochloride, which is marketed and sold in the United States under

the trade name Paxil. GSK denies the remaining allegations contained in Paragraph 91 of Plaintiffs' Long-Form Complaint.

92. GSK states that the allegations contained in Paragraph 92 of Plaintiffs' Long-Form Complaint, including subparagraphs (a) through (h), are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies the allegations contained in Paragraph 92 of Plaintiffs' Long-Form Complaint, including subparagraphs (a) through (h).

93. Answering Paragraph 93 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 93 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies it is responsible in any way for causing or contributing to any alleged injuries or damages to Plaintiffs. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 93 of Plaintiffs' Long-Form Complaint, particularly as they relate to Kaden Cotes' injuries, and therefore denies the same.

94. Answering Paragraph 94 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 94 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies that it responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining

allegations contained in Paragraph 94 of Plaintiffs' Long-Form Complaint and therefore denies the same.

95. Answering Paragraph 95 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 95 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies that it responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 95 of Plaintiffs' Long-Form Complaint and therefore denies the same.

96. Answering Paragraph 96 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 96 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies that it responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 96 of Plaintiffs' Long-Form Complaint and therefore denies the same.

97. GSK denies the allegations contained in Paragraph 97 of Plaintiffs' Long-Form Complaint.

The unnumbered WHEREFORE paragraph following Paragraph 97 is a prayer for relief to which GSK responds that Plaintiffs are not entitled to any relief from GSK, including all relief in this prayer for relief.

**ANSWERING THE SECTION OF PLAINTIFFS' MASTER
LONG-FORM COMPLAINT TITLED "COUNT XI: WRONGFUL DEATH"**

98. GSK incorporates by reference, as if set forth fully herein, its responses to all preceding Paragraphs in this Answer and each and every one of its defenses.

99. Answering Paragraph 99 of Plaintiffs' Long-Form Complaint, GSK denies that it is responsible in any way for causing or contributing to the alleged injuries or damages. GSK denies any remaining allegations contained in Paragraph 99 of Plaintiffs' Long-Form Complaint.

100. Answering Paragraph 100 of Plaintiffs' Long-Form Complaint, GSK admits that Plaintiffs seek damages for alleged injuries. GSK states that the allegations contained in Paragraph 100 of Plaintiffs' Long-Form Complaint are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph contains factual allegations directed to GSK, GSK denies that it responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 100 of Plaintiffs' Long-Form Complaint and therefore denies the same.

101. GSK denies the allegations contained in Paragraph 101 of Plaintiffs' Long-Form Complaint.

The unnumbered WHEREFORE paragraph following Paragraph 101 is a prayer for relief to which GSK responds that Plaintiffs are not entitled to any relief from GSK, including all relief in this prayer for relief.

**ANSWERING THE SECTION OF PLAINTIFFS' MASTER
LONG-FORM COMPLAINT TITLED "COUNT XII: DAMAGES"**

102. GSK incorporates by reference, as if set forth fully herein, its responses to all preceding Paragraphs in this Answer and each and every one of its defenses.

103. Answering Paragraph 103 of Plaintiffs' Long-Form Complaint, GSK denies that it is responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK denies any remaining allegations contained in Paragraph 103 of Plaintiffs' Long-Form Complaint.

104. Answering Paragraph 104 of Plaintiffs' Long-Form Complaint, GSK denies that it is responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK denies any remaining allegations contained in Paragraph 104 of Plaintiffs' Long-Form Complaint.

105. Answering Paragraph 105 of Plaintiffs' Long-Form Complaint, GSK denies that it is responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK denies any remaining allegations contained in Paragraph 105 of Plaintiffs' Long-Form Complaint.

106. Answering Paragraph 106 of Plaintiffs' Long-Form Complaint, GSK denies that it is responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK denies any remaining allegations contained in Paragraph 106 of Plaintiffs' Long-Form Complaint.

107. Answering Paragraph 107 of Plaintiffs' Long-Form Complaint, GSK denies that it is in any way liable for any alleged injuries to Plaintiffs. GSK further states that the allegations contained in Paragraph 107 of Plaintiffs' Long-Form Complaint, are conclusions of law to which no response is required and which are denied as a matter of law. To the extent this Paragraph

contains factual allegations directed to GSK, GSK denies the allegations contained in Paragraph 107 of Plaintiffs' Long-Form Complaint.

108. Answering Paragraph 108 of Plaintiffs' Long-Form Complaint, GSK denies that it is responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK denies any remaining allegations contained in Paragraph 108 of Plaintiffs' Long-Form Complaint.

109. Answering Paragraph 109 of Plaintiffs' Long-Form Complaint, GSK denies that it is responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK denies any remaining allegations contained in Paragraph 109 of Plaintiffs' Long-Form Complaint.

110. Answering Paragraph 110 of Plaintiffs' Long-Form Complaint, GSK admits that a lawsuit has been filed against it by Plaintiff Christine Hess on behalf of Kaden Cotes. GSK denies that it is responsible in any way for causing or contributing to any injuries or damages alleged in Plaintiffs' Long-Form Complaint. GSK denies any remaining allegations contained in Paragraph 110 of Plaintiffs' Long-Form Complaint.

**ANSWERING THE SECTION OF PLAINTIFFS' MASTER
LONG-FORM COMPLAINT TITLED "COUNT XII: PUNITIVE DAMAGES"**

111. GSK incorporates by reference, as if set forth fully herein, its responses to all preceding Paragraphs in this Answer and each and every one of its defenses.

112. GSK denies the allegations contained in Paragraph 112 of Plaintiffs' Long-Form Complaint.

113. GSK denies the allegations contained in Paragraph 113 of Plaintiffs' Long-Form Complaint.

114. GSK denies the allegations contained in Paragraph 114 of Plaintiffs' Long-Form Complaint.

115. GSK denies the allegations contained in Paragraph 115 of Plaintiffs' Long-Form Complaint.

ANSWERING THE SECTION OF PLAINTIFFS' MASTER LONG-FORM COMPLAINT TITLED "PRAYER"

GSK denies that Plaintiffs are entitled to a judgment against GSK or to recover from GSK the damages and other relief sought in the "Prayer," including subparagraphs (A) through (I).

GENERAL DENIAL

Pursuant to Federal Rule of Civil Procedure 8(b), GSK denies that Plaintiffs have been damaged in any sum, or at all, by reason of any act or omission on the part of GSK, and denies all allegations of Plaintiffs' Complaint except those that have been specifically admitted.

AFFIRMATIVE DEFENSES

Subject to its general and specific denials, and without waiving the same, GSK asserts the following affirmative defenses:

FIRST DEFENSE

(Failure to State a Cause of Action)

Plaintiffs' Complaint fails, in whole or in part, to state a claim upon which relief may be granted.

SECOND DEFENSE

(Preemption)

Plaintiffs' claims are preempted or barred, in whole or in part, by the Federal Food, Drug and Cosmetics Act as amended, including but not limited to the doctrine of primary jurisdiction

because the Food and Drug Administration of the United States Department of Health (“FDA”) has primary jurisdiction over the issues raised in Plaintiffs’ Complaint and exclusive regulatory control of products such as the product at issue here. The granting of the relief prayed for in Plaintiffs’ Complaint would impede, impair, frustrate, or burden the effectiveness of such federal law and would violate the Supremacy Clause (Art. VI, cl. 2) of the United States Constitution, and the Court should either dismiss these claims for relief or defer consideration of them to FDA.

THIRD DEFENSE

(No Private Cause of Action)

Plaintiffs’ Complaint fails to state a claim against GSK because there is no private right of action under the Federal Food, Drug, and Cosmetics Act as amended.

FOURTH DEFENSE

(First Amendment: Right to Petition the Government)

To the extent Plaintiffs’ claims are based on alleged communications between GSK and regulatory agencies of the United States government or any other government, those claims are barred, in whole or in part, by operation of applicable law, including the First Amendment rights of GSK to petition the government.

FIFTH DEFENSE

(First Amendment: Freedom of Speech)

Plaintiffs’ claims are barred in whole or in part because the commercial speech of GSK relating to Paxil is not false or misleading and is protected under the First Amendment to the United States Constitution.

SIXTH DEFENSE

(Regulatory Compliance)

Plaintiffs' claims are barred, in whole or in part, because GSK complied with applicable statutes and with the requirements and regulations of the Food and Drug Administration. See, e.g., U.S. Const. Art. VI, cl. 2.

SEVENTH DEFENSE

(Lack of Negligence or Defect)

GSK specifically denies that it was negligent in any manner and specifically denies that it produced or distributed any unreasonably dangerous or defective product.

EIGHTH DEFENSE

(Reasonably Safe)

Plaintiffs' alleged causes of action are barred because, based upon the scientific skill and knowledge at the time the subject product was distributed, the subject product was reasonably safe for normal and foreseeable use and the benefits of the product outweighed any associated risks.

NINTH DEFENSE

(Inherent Characteristics of the Product)

Plaintiffs' alleged damages, if they were caused by the product, which GSK expressly denies, were caused by a generic, inherent characteristic of the product that could not be eliminated without substantially compromising the product's usefulness or desirability and which is recognized by the ordinary person with the ordinary knowledge common to the community.

TENTH DEFENSE

(Assumption of Risks)

Plaintiffs may have knowingly and voluntarily assumed any and all risks with the use of the product at issue in this case and such assumption of risk bars, in whole or in part, the damages Plaintiffs seeks to recover herein.

ELEVENTH DEFENSE

(Pre-existing Conditions)

Plaintiffs' alleged injuries or damages, if any, may have been caused by an idiosyncratic reaction, without any negligence or failure on the part of GSK or any defect attributable to its product, and Plaintiffs' claims are therefore barred.

TWELVTH DEFENSE

(Idiosyncratic Reaction)

Plaintiffs' alleged injuries or damages, if any, may have been caused by an idiosyncratic reaction, without any negligence or failure on the part of GSK or any defect attributable to its product, and Plaintiffs' claims are therefore barred.

THIRTEENTH DEFENSE

(Failure to Exercise Ordinary Care)

Plaintiffs may have failed to exercise ordinary care or reasonable care. If so, Plaintiffs' Complaint should be dismissed or the damages reduced under the doctrine of contributory negligence and/or comparative fault.

FOURTEENTH DEFENSE

(Comparative Negligence/Fault)

GSK invokes the defense of comparative negligence/fault. GSK states that if Plaintiffs sustained any injuries or damages, which fact is specifically denied, and it is determined that said injuries or damages were caused, in whole or in part, by the acts, omissions, negligence, or fault of other persons or entities for whom GSK is not responsible, and if such acts, omissions, negligence, or fault do not act as a complete bar to Plaintiffs' claims against GSK, then GSK is entitled to an apportionment of all such causal fault and a reduction of any award against it.

FIFTHEENTH DEFENSE

(Good Faith)

Plaintiffs' claims are barred because any alleged representations and/or conduct on the part of GSK were made in good faith and were not intended to deceive Plaintiffs.

SIXTEENTH DEFENSE

(Misuse)

If Plaintiffs sustained injuries attributable to the use of the product at issue in this case, which allegations are expressly denied, the injuries were solely caused by and attributable to the unintended, unreasonable, and improper use, misuse, alteration, or modification which was made of said product.

SEVENTEENTH DEFENSE

(Benefits Outweigh Risks)

The benefits of Paxil outweigh the risks, if any, which may be attendant to its use, and public policy dictates against holding GSK responsible for any alleged injuries sustained by Plaintiffs.

EIGHTEENTH DEFENSE

(Failure to Give Notice)

Plaintiffs failed to give timely notice of any alleged breach of warranty, whether express or implied.

NINETEENTH DEFENSE

(Lack of Privity)

Plaintiffs' alleged claims for breach of warranty are barred by lack of privity of contract between Plaintiffs and GSK.

TWENTIETH DEFENSE

(Denial of Warranties)

GSK denies that it made any express or implied warranties.

TWENTY-FIRST DEFENSE

(No Reliance on Warranties)

Plaintiffs did not rely on any alleged warranties.

TWENTY-SECOND DEFENSE

(Intervening and Superseding Causes)

The damages and injuries allegedly sustained by Plaintiffs, if any, were not legally caused by the product at issue, but instead were legally caused by intervening and superseding causes or circumstances.

TWENTY-THIRD DEFENSE

(Failure to Mitigate)

Plaintiffs' damages, if any, are barred in whole or in part by Plaintiffs' failure to mitigate such damages.

TWENTY-FOURTH DEFENSE

(Statute of Limitations)

Each of the purported claims in Plaintiffs' Complaint may be barred by the applicable statute of limitations or repose.

TWENTY-FIFTH DEFENSE

(State-of-the-Art)

At all times material thereto, GSK's conduct conformed to the state-of-the-art.

TWENTY-SIXTH DEFENSE

(Equitable Defenses)

Plaintiffs' claims are barred in whole or in part by the doctrines of laches, estoppel, waiver, unclean hands, and/or failure to preserve evidence.

TWENTY-SEVENTH DEFENSE

(Res Judicata and Collateral Estoppel)

Plaintiffs' claims are barred by the doctrines of res judicata and/or collateral estoppel.

TWENTY-EIGHTH DEFENSE

(Set Off)

Plaintiffs' claims are barred as a whole or in part to the extent Plaintiffs have released, settled, entered into accords and satisfaction, or otherwise compromised their claims. Any recovery by Plaintiffs must be reduced or offset by amounts Plaintiffs have received or will receive from others for the same injuries claimed in this lawsuit.

TWENTY-NINTH DEFENSE

(Use in Contravention of Warning)

Plaintiffs' alleged damages, if caused by the subject product, which GSK expressly denies, were caused by use of the product in contravention of warnings provided with it.

THIRTIETH DEFENSE

(Restatement of Torts (Second) Section 402A

and Restatement (Third) of Torts: Products Liability Section 6)

GSK pleads the application of Comments j and k to the Restatement (Second) of Torts § 402A and the application of Restatement (Third) of Torts: Products Liability § 6. GSK provided adequate warnings and complete warnings to Plaintiffs' prescribing physicians and, therefore, the product was not defective or unreasonably dangerous.

THIRTY-FIRST DEFENSE

(Learned Intermediary Doctrine)

Plaintiffs' claims are barred, in whole or in part, by the Learned Intermediary Doctrine.

THIRTY-SECOND DEFENSE

(Adequate Warnings)

Adequate and complete warnings and instructions were provided with the subject product, and the subject product was neither defective nor unreasonably dangerous when used according to label instructions.

THIRTY-THIRD DEFENSE

(Failure to Plead Fraud with Particularity)

To the extent Plaintiffs' claims are based on alleged fraud and misrepresentation, they must be dismissed because Plaintiffs failed to plead those claims with the required particularity.

THIRTY-FOURTH DEFENSE

(No Private Cause of Action for “Fraud on FDA”)

To the extent Plaintiffs’ claims are based on alleged misrepresentations or omissions made to FDA, such claims are barred pursuant to pursuant to Buckman Co. v. Plaintiffs’ Legal Comm., 531 U.S. 341 (2001).

THIRTY-FIFTH DEFENSE

(Claims Based on Fraud or Fraudulent Misrepresentation are Barred)

To the extent Plaintiffs’ claims are based on fraud or fraudulent misrepresentation, such claims are barred because Plaintiffs have not pointed to any alleged representations and actions that were material or otherwise likely to mislead consumers or healthcare providers acting reasonably under the circumstances. Further, Plaintiffs have not pointed to any alleged representations or actions that did or were likely to either affect Plaintiffs’ decisions and/or conduct or proximately and/or actually cause consumers, or Plaintiffs, to act differently.

THIRTY-SIXTH DEFENSE

(Pain and Suffering Barred by Constitution)

To the extent that Plaintiffs claims damages for pain and suffering, such claims are barred because they violate GSK’s right to due process and equal protection under the United States Constitution.

THIRTY-SEVENTH DEFENSE

(Due Process; Equal Protection)

With respect to Plaintiffs’ demand for punitive damages, the imposition of punitive damages would violate GSK’s right to due process under the Fifth and Fourteenth Amendments

to the United States Constitution, and GSK's right to equal protection under the Fourteenth Amendment to the United States Constitution

THIRTY-EIGHTH DEFENSE

(Punitive Damages; Lack of Specificity)

With respect to Plaintiffs' demand for punitive damages, Plaintiffs have failed to allege punitive damages with the requisite specificity.

THIRTY-NINTH DEFENSE

(Due Process)

With respect to Plaintiffs' demand for punitive damages, punitive damages are a punishment, a quasi-criminal sanction for which GSK has not been afforded the specific procedural safeguards prescribed in the Fifth and Sixth Amendments to the United States Constitution.

FORTIETH DEFENSE

(Punitive Damages; Limitation on Awards)

With respect to Plaintiffs' demand for punitive damages, GSK specifically incorporates by reference all standards and/or limitations regarding the determination and enforceability of punitive damage awards which arose in the decisions of BMW of North America v. Gore, 517 U.S. 559 (1996); Cooper Industries, Inc. v. Leatherman Tool Group, Inc., 532 U.S. 424 (2001), and State Farm Mutual Automobile Insurance Co. v. Campbell, 538 U.S. 408 (2003).

FORTY-FIRST DEFENSE

(Punitive or Exemplary Damages)

Plaintiffs are not entitled to punitive or exemplary damages.

FORTY-SECOND DEFENSE

(Punitive Damages; Lack of Prior Notice)

Consideration of any punitive damages in this civil action would violate the due process clauses of the Fifth and Fourteenth Amendments to the United States Constitution by allowing standardless discretion to the jury to determine punishment and by depriving GSK of prior notice of the consequences of its alleged acts.

FORTY-THIRD DEFENSE

(Excessive Fines)

With respect to Plaintiffs' demand for punitive damages, Plaintiffs are not entitled to collect an award of punitive damages from GSK because an award of such damages could violate the excessive fines clauses of the United States Constitution.

FORTY-FOURTH DEFENSE

(Speculative Damages)

Plaintiffs' claims are barred to the extent the alleged damages are too speculative to be recoverable at law.

FORTY-FIFTH DEFENSE

(Indebtedness)

GSK is not indebted or liable to Plaintiffs in any manner or amount whatsoever.

FORTY-SIXTH DEFENSE

(Doctrine of Avoidable Consequences)

Plaintiffs' damages are barred or reduced by the doctrine of avoidable consequences.

FORTY-SEVENTH DEFENSE

(Consumer Expectations)

Plaintiffs' claims are barred, in whole or in part, by the lack of a defect under the consumer expectations test. The consumer expectations test is not applicable in this action.

FORTY-EIGHTH DEFENSE

(Venue)

Venue may be improper.

FORTY-NINTH DEFENSE

(Adequate Remedy at Law)

Any claims Plaintiffs may make for equitable relief are barred because Plaintiffs have an adequate remedy at law.

FIFTIETH DEFENSE

(Applicable State Law)

GSK asserts any and all defenses available under Louisiana law applicable to product liability actions, including but not limited to the Louisiana Products Liability Act, La. Rev. Stat. § 9:2800.51 *et seq.*

FIFTY-FIRST DEFENSE

(Laws of Other States)

To the extent that the law of any other State applies to some or all of the Plaintiffs' purported claims, GSK incorporates and adopts on its behalf all defenses that would be available as a matter of law, statute, or regulation under the law of such State.

FIFTY-SECOND DEFENSE

(Other Defenses)

GSK hereby gives notice that it intends to rely upon such other defenses as may become available or appear during discovery in this case or otherwise, and hereby reserves the right to amend this Answer to assert any such defenses.

PRAYER FOR RELIEF

WHEREFORE, GSK prays that:

- (a) This Court enter judgment in its favor and against Plaintiffs'
- (b) GSK recover its costs and expenses, including attorneys' fees; and
- (c) This Court award GSK such other and further relief as the Court may deem just and proper.

JURY DEMAND

GSK hereby invokes its right to trial by jury.

Dated this 12th day of October, 2010.

Respectfully submitted,

LAVIN, O'NEIL, RICCI, CEDRONE & DISIPIO

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CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of October, 2010, I caused to be served via ECF Filing and/or U.S. Mail a true and correct copy of the foregoing **DEFENDANT**
GLAXOSMITHKLINE LLC, FORMERLY SMITHKLINE BEECHAM CORPORATION
D/B/A GLAXOSMITHKLINE'S ANSWER AND AFFIRMATIVE DEFENSES TO
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